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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,913	09/25/2003	Matthew S. Solar	723.061US1	8466

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,913

Applicant(s)

SOLAR ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-20, 22-28 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 13, 24, 26-28 and 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9, 11, 12, 14-20, 22, 23 and 25 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 29 May 2007.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 May 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 5, 6, 9, 11, 12, 14-20, 22, 23, and 25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 11 is objected to because of the following informalities: the limitation "wherein the standoff features are located adjacent to the number of securing devices" is unclear. As shown in Figure 3A of the instant application, the securing features are located within the standoff features. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3, 5, 6, 9, 11, 12, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (Patent No. 5,752,962) in view of Mowlai-Ashtiani (Patent No. 6,110,182). D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (for example, see Figure 4; element 27), a spherical portion (26), a base unit (20), a spherical socket (25), an actuating device (threaded screw 30 comprises a "threaded ring"), three standoff features (21) capable of contacting the work surface (24) along a circle, a shelf (22) having an attachment thickness less than the standoff feature thickness (for example, see Figure 4), a number of securing devices (bone screws in apertures 23), and screw retention features (internal threading of apertures 23). The spherical socket (25) is deformable in that it deforms to an extent when the actuating device (30) is actuated. D'Urso fails to disclose the actuating device is not in direct contact with the spherical portion and that the spherical socket includes relief openings.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), a deformable socket (10; via attachment 78; column 3, lines 45-51), and an actuating device (52). Mowlai-Ashtiani teaches the

actuating device (52) is not in direct contact with the spherical portion (32), the spherical socket (12) contains three relief openings (22; for example, see Figure 2), and the actuating device (52) provides symmetric tightening of the spherical socket (12) around the spherical portion (column 2, lines 15-18 and 50-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of D'Urso such that the spherical socket includes relief openings, and the actuating device is not in direct contact with the spherical portion as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the device (for example, see column 3, lines 40-44 and column 2, lines 19-27).

With further respect to claims 18-20, D'Urso in view of Mowlai-Ashtiani discloses a screw retention feature (see rejection above), but does not disclose expressly that the screw retention feature includes an elastomer band or a protruding structure located external to and above an opening. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to utilize an elastomer band or a protruding structure located external to and above an opening. There are numerous retention features well known in the art and applicant has not disclosed that an elastomer band or a protruding structure located external to and above an opening provides an advantage, is used for a particular purpose, or solves a stated problem. For example, Coates et al. (Patent No. 5,423,826) discloses a structure (Figure 6; O-ring 69 formed of biocompatible elastomeric material, thus comprises an "elastomer band"; column 9, lines 39-40) that protrudes into a portion of a screw opening and is strong enough to resist screw pull out (column 9, lines 33-44). Magee et al. (Patent No.

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5,957,927) discloses a screw retention feature (retaining element 62, Figure 10; column 5, lines 31-34) that is located external to, and above screw opening (34). Therefore, it would have been obvious to one of ordinary skill in the art to modify the retention features of D'Urso in view of Mowlai-Ashtiani to obtain the invention as specified in claims 18-20.

2. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso in view of Mowlai-Ashtiani as applied to the claims above, and further in view of Ghajar et al. (Patent No. 4,998,938). D'Urso in view of Mowlai-Ashtiani fails to disclose the standoff features are cone shaped. Ghajar et al. teach cone shaped standoff features (wider on top and narrower towards the bottom). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize cone shaped standoff features in the device of D'Urso in view of Mowlai-Ashtiani as taught by Ghajar et al. in order to support the base unit (via the large surface area) and minimize contact with respect to the patient's scalp and cranium (via the smaller surface area) during the procedure, thus reducing the risk of infection to the surrounding tissue (column 2, lines 44-48).

3. Claims 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso in view of Mowlai-Ashtiani, and further in view of Hennig (Patent No. 6,328,748). D'Urso discloses an alignment device (see entire document) comprising a longitudinal guide portion (for example, see Figure 4; element 27), a spherical portion (26), a base unit (20), a spherical socket (25), an actuating device (threaded screw 30 comprises a "threaded ring"), three standoff features (21) capable of

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contacting the work surface (24) along a circle, a shelf (22) having an attachment thickness less than the standoff feature thickness (for example, see Figure 4), a number of securing devices (bone screws in apertures 23), and screw retention features (internal threading of apertures 23). The spherical socket (25) is deformable in that it inherently deforms to an extent when the actuating device (30) is actuated. D'Urso fails to disclose that the spherical socket includes relief openings.

Mowlai-Ashtiani discloses an alignment device (see entire document) comprising a guide portion (72), a spherical portion (32), a deformable socket (10; via attachment 78; column 3, lines 45-51), and an actuating device (52). Mowlai-Ashtiani teaches the spherical socket (12) contains three relief openings (22; for example, see Figure 2) and the actuating device (52) provides symmetric tightening of the spherical socket (12) around the spherical portion (column 2, lines 15-18 and 50-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of D'Urso such that the spherical socket includes relief openings as taught by Mowlai-Ashtiani. Doing so would allow a user to easily manipulate the device (for example, see column 3, lines 40-44 and column 2, lines 19-27).

D'Urso in view of Mowlai-Ashtiani fails to disclose an insert. Hennig discloses an alignment device (see entire document). Hennig teaches an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It would have been obvious to one of ordinary skill in the art at the time the

invention was made to utilize an insert in the device of D'Urso in view of Mowlai-Ashtiani as taught by Hennig in order to size the longitudinal opening in the longitudinal guide with the specific equipment that is to be passed there through (column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a biopsy probe since it is well known in the art to utilize probes in surgery (for example, see Mowlai-Ashtiani column 4, lines 31-34).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
August 1, 2007

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SUPERVISORY PATENT EXAMINER